

**REMARKS/ARGUMENTS**

This paper is submitted in response to the Office Action dated February 24, 2004. Claims 1-26 and 28 are pending in the present application. Claims 1-3, 5-22 and 28 stand rejected under 35 U.S.C. §102(b) as being unpatentable over U.S. Patent No. 6,264,629 to Landau. Claims 1-22, and 28 stand rejected under 35 U.S.C. §102(b) as being unpatentable over U.S. Patent Application No. 2001/0004681 by Landau. The Examiner has rejected Claims 17-22 under 35 U.S.C. §103(a) as being unpatentable over '629 to Landau in view of U.S. Patent Application Publication No. 2003/0093030 by Landau. Claim 23 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Landau. Claims 24-26 stand rejected under 35 U.S.C. §103(a) as being unpatentable over '629 to Landau in view of U.S. Patent No. 6,752,781 to Landau.

Initially, Applicant would like the Examiner for the courtesies extended during the telephone interview held on June 22, 2006, between the Examiner and the undersigned. During that telephone conference, distinctions between the claimed invention and the cited references were discussed. In particular, the undersigned argued that, of the cited references, only the Landau '781 patent discussed drawing a medication into a nozzle of an injection device. Furthermore, the undersigned argued that the claimed structure to enable a desired dose of medicament to be drawn into the nozzle ready for injection, was not taught, suggested or disclosed by the cited references. The undersigned further argued that a guide means for guiding the axial movement of the recited housings enabling a desired dose of medicament to be drawn into the nozzle, as recited by Claim 5, and the indication of the dose of medicament which is drawn into the device, recited by Claim 7, are also not taught, suggested or described by the cited references. No agreement regarding allowable subject matter was reached.

Fundamental to the understanding of the claimed invention is that it is a disposable gas-powered needle-free injection device having an axially-movable inner housing which can be used to draw a desired dose of liquid medicament into the device ready for delivery into the patient.

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Previously, such disposable gas-powered needle-free devices utilised a pre-filled and sealed cartridge or cylinder of liquid medicament which is preloaded into the device. Such preloaded devices do not permit the user to select the desired dose immediately prior to injection (in other words, the only “dosing” occurs through the choice of device having a predetermined dose therein).

### **Claim Rejections – 35 USC § 102**

Claims 1-3, 5-22 and 28 stand rejected under 35 U.S.C. §102(b) as being unpatentable over U.S. Patent No. 6,264,629 to Landau. Additionally, Claims 1-22, and 28 stand rejected under 35 U.S.C. §102(b) as being unpatentable over U.S. Patent Application Publication No. 2001/0004681 by Landau. It is well recognized that claims are anticipated if, and only if, each and every element, as set forth in the claim is found in a single prior art reference. Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Furthermore, “[t]he identical invention must be shown in as complete detail as is contained in the . . . claim.” Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). See MPEP § 2131. To constitute anticipation, all material elements of the claim must be found in one prior art source. In re Marshall, 198 USPQ 344 (CCPA 1978); In re Kalm, 154 USPQ 10 (CCPA 1967). Additionally, the elements of the reference must be arranged as required by the claim. In re Bond, 15 USPQ 2d 1566 (Fed. Cir. 1990). Applicant respectfully submits that the cited references do not teach all of the material elements and do not arrange the elements as required by the rejected claim language.

U.S. Pat. No. 6,264,629 discloses “a drug injection cartridge which provides a cylinder of liquid medication to be injected” [abstract]. The field of the invention section says at column 1 lines 15-18 “Particularly, this invention relates to...a hand-held injector having a pre-filled drug cartridge sealingly carrying injectable medication”. There is no teaching whatsoever in Landau ‘629 regarding the possibility of adapting such a device to permit dosing by the patient.

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Regarding the volume of medicament to be delivered, the only teaching is that the dose is determined by the size of pre-filled drug injection cartridge 14. According to column 6, lines 33-35, “the chamber 52 is sealed and is substantially full of incompressible liquid”. Claim 1 of Landau ‘629 also defines the “dose” in terms of the size of the chamber in the pre-filled drug injection cartridge.

U.S. Application Publication No. 2001/0004681 is a continuation in part of Landau ‘629 and the above paragraph applies equally here. In particular, there is no teaching in Landau ‘681 regarding the possibility of adapting such a device to permit dosing by the patient.

The Office Action equates body portion 12c with the claimed “inner housing” but the body portion 12c is entirely unconnected with determining the dose of medicament in the device. Neither the Landau ‘629 nor the Landau ‘681 reference discloses an inner housing “axially moveable away from the nozzle, said axial movement being guided by cooperating guide means on said inner and outer housings and enabling a desired dose of medicament to be drawn into said nozzle ready for injection”. Consequently neither claim 1 nor any of its dependent claims are anticipated by either of these references.

It is submitted that the Office Action does not provide a single reference that contains each and every element as set forth in the above claims. Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. §102(b) are respectfully requested.

### **Claim Rejections – 35 USC § 103**

The Examiner has rejected Claims 17-22 under 35 U.S.C. §103(a) as being unpatentable over ‘629 to Landau in view of U.S. Patent Application Publication No. 2003/0093030 by Landau. Claim 23 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Landau. Additionally, the Examiner has rejected Claims 24-26 under 35 U.S.C. §103(a) as being unpatentable over ‘629 to Landau in view of U.S. Patent No. 6,752,781 to Landau. To establish a *prima facie* case of obviousness under 35 U.S.C. §103(a), the Examiner must show that 1) the

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references teach all of the elements of the claimed invention, 2) the references contain some teaching, suggestion or motivation to combine the references, and 3) the references suggest a reasonable expectation of success. See MPEP § 2142; see also, In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991); In re Kotzab, 217 F.3d 1365, 55 USPQ2d 1313 (Fed. Cir. 2000).

U.S. Application Publication No. 2003/0093030 discloses a disposable gas-powered needle-free injection device having an “injectate storage chamber 58” in the first embodiment. As is apparent from paragraph 30, the chamber is pre-loaded with medicament before being shipped to the patient. The second embodiment has an injectate storage sleeve/cylinder 146. Storage sleeve 146 typically takes the form of a glass cylinder [paragraph 28] and is also pre-filled before shipping [paragraph 37]. Therefore, as in the above references, the device is not dosable. Consequently, it is believed that the 35 USC § 103 rejections of claims 17-22 are moot in view of the arguments above re Landau ‘629 and Landau ‘030.

U.S. Application Publication App. No. 2002/0188250 (now U.S. Pat. No. 6,752,781) discloses a gas-powered durable needle-less injection device. Note that the device is “durable” i.e. intended for multiple-uses rather than being disposable, although paragraph 28 states that the device could be used only once if desired. Because the device is capable of being used more than once, this is the only cited device that requires loading or dosing by the patient prior to injection. As described in paragraph 29, the patient attaches a medicine vial from which the required dose is drawn into the injection cylinder 14. However, whereas in the claimed invention, guided axial movement of an inner housing away from the nozzle causes the dose to be drawn in, in Landau ‘781 it is thumbwheel 28 which effects rearward movement of the piston 16 within cylinder 14 that causes medication to be drawn in. Thumbwheel 28 cannot be equated with “an inner housing located at least partly within the outer housing” and “axially moveable away from said nozzle” as required by claim 1. Furthermore, the piston 16 and the associated ram 26 are not an

“inner housing” as claimed. Additionally, the arguments above re Landau ‘629 are believed to make this rejection moot.

It is unclear as to which Landau reference the Office Action cites in relation to claim 23. However, as stated above, all of the Landau references fail to disclose a device that both permits dosing by the patient and contains an “inner housing located at least partly within the outer housing” and “axially moveable away from the nozzle.”

It is submitted that the Office Action has failed to establish a *prima facie* case of obviousness under 35 U.S.C. §103(a). Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. §103(a) are respectfully requested.

In addition, at least some of the dependent claims recite additional patentable subject matter. For example, Claim 5 recites that the guide means for guiding the axial movement of the inner housing away from the nozzle comprises a substantially helical groove in the outer housing and a corresponding protrusion on the inner housing. However, the cited references do not disclose a structure in which a helical groove and a corresponding protrusion guide movement of an inner housing relative to an outer housing to enable a desired dose of medicament drawn into the nozzle. Accordingly, for at least this additional reason dependent Claim 5 and the claims dependent therefrom (i.e. Claims 6-10) should be.

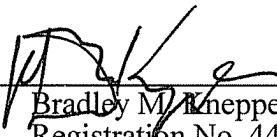
Dependent Claim 7 additionally recites a flexible indexer tab which can ride over a helical arrangement of discrete teeth in order to provide a dose indication. The references that have been cited in the Office Action do not teach, suggest or describe such features. The Landau ‘681 publication discusses visual and auditory indications of the condition of the device (i.e. whether the device trigger is ready to effect an injection.) (Landau ‘681, paragraph 82.) However, these features of the Landau ‘681 reference, do not provide an indication of the dose of medicament drawn into the device. Accordingly, for at least these additional reasons, Claim 7 and the claims dependent therefrom (i.e. Claims 8-10) should be allowed.

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Based upon the foregoing, Applicants believe that all pending claims are in condition for allowance and such disposition is respectfully requested. In the event that a telephone conversation would further prosecution and/or expedite allowance, the Examiner is invited to contact the undersigned.

Respectfully submitted,

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